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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,573	06/24/2003	Yu-Chong Tai	020859-002410US	3326
22428	7590	12/15/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			RAMILLANO, LORE JANET	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/603,573

Applicant(s)

TAI ET AL.

Examiner

Lore Ramillano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 34-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☒ Claim(s) 1-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/24/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/06, 8/11/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Election/Restrictions**

1. Applicant's election with traverse of Group I, claims 1-33 in the reply filed on 10/16/06 is acknowledged. The traversal is on the ground(s) that the restriction requirement noted an unspecified species election issue on page 5 of the prior Office Action, filed on 6/14/06. This is not found persuasive because it is believed that applicant misunderstood the election requirement on page 5. The paragraphs on page 5 of the prior Office Action state that applicant is advised to elect "a species or invention." In addition, the previous paragraphs in this Office Action refer to five independent or distinct inventions (Groups I-V) and do not include any language referring to a patentably distinct species.

Thus, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 34-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/16/06.

### **Claim Objections**

3. Claims 1-33 are objected to because of the following informalities: In claim 1, line 13, "an separation column" and "an micro-" should be changed to "a separation column" and "a micro-." In claim 8, line 3, "an sample injector," should be changed to "a sample injector." Appropriate corrections are required.

### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 11-20, 23-24, and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because applicant's specification does not provide support that the claimed sample injector is one of the electrolysis pumps. If applicant intends to claim that the sample injector is an electrolysis pump, then examiner will interpret "sample injector" and "electrolysis pump" as being the same.

Claims 14-16 are indefinite because it cannot be determined what volume range of the chamber applicant is claiming. These claims are confusing because the fluid is measured in  $\mu\text{l}$  in claim 14 and  $\mu\text{m}$  in claims 15-16.

Examiner suggests replacing "characterized" in claims 17-19 with the following transitional phrases, "comprising."

Claim 20 is indefinite because it is unclear what applicant is claiming. Because including is an open-ended transitional phrase, the chamber and separation column may be made of any material including Parylene. Thus, examiner suggests rewording the language in this claim.

Claims 20-21 are indefinite because the terms, "Parylene" and "Teflon" are trademarks, which are not subject to constraint and therefore make the metes and bounds of the claim unclear. Applicant must replace the terms with generic terminology.

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Claim 23 is indefinite because it is unclear what applicant is claiming since it appears applicant is claiming all types of liquids.

Claim 27 is indefinite because it is unclear what applicant means by reciting a "separate substrate." Furthermore, it is unclear how this claim further limits claim 27 since it appears that this claim recites the same language recited in lines 17-19 of claim 1.

Claims 28-29 are indefinite because it is unclear what "separate components" means. Furthermore, claim 29 is confusing because it cannot be determined what structural limitations are being claimed.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

### **Claim Rejections - 35 USC § 102**

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-4, 6-23, and 25-33** are rejected under 35 U.S.C. 102(e) as being anticipated by Lazar et al. ("Lazar," US Pub. No. 2004/0208751).

Lazar discloses the structural limitations of applicant's invention. In particular, Lazar discloses a microfluidic system comprising a substrate (i.e. microchip platform, [0026]), an electrochemical pump system on the substrate, the electrochemical pump system comprising a plurality of electrolysis pumps, in which one is a sample injector, configured in parallel and/or sequential (i.e. [0026]) and having at least one outlet; each of the electrolysis pumps comprising: a chamber (i.e. [0038]); a plurality of electrodes, which are coupled to an electrical source (i.e. 30, high voltage power source, [0027]); a fluid comprising of the same or different fluids is inside the chamber, which is contacted with the electrodes (i.e. [0028], [0068]); an inlet and an outlet (i.e. 14, 16, [0027]); a separation column on the substrate having an inlet, an outlet, a microchannel, a solid stationary phase material packed inside the microchannel, the inlet of the separation column being coupled to at least one outlet of the electrochemical pump; and wherein the electrochemical pump system and the separation column are configured such that the electrochemical pump system provides an elution for a separation process (i.e. [0029], [0031], [0061]).

Lazar further discloses: a gradient elution (i.e. [0047]), a sample source (i.e. [0029]), mixers (i.e. [0026]), a nozzle (i.e. 32, [0029]) that is coupled to an electrospray ionization-mass spectrometry (ESI-MS) (i.e. [0026]), a detection device (i.e. optical detectors, [0026]), and a pump system and separation column constructed from injection molding, photolithography, dry etching, wet etching, and other microfabrication techniques (i.e. [0037]).

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### Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 5 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazar in view of Kaduce et al. ("Kaduce," *A rapid, isocratic*

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*method for phospholipids separation by high-performance liquid chromatograph, 1983).*

Lazar discloses the following: see paragraph 7 above.

Lazar does not specifically disclose utilizing an isocratic elution and a fluid that is selected from a group consisting of acetonitrile, methanol, ethanol, tetrahydrofuran, isopropanol, and toluene.

Kaduce discloses a rapid, isocratic method for separating the most prevalent phospholipids by high-performance liquid chromatography. Kaduce further discloses utilizing acetonitrile and methanol to conduct the HPLC analysis (i.e. page 1398, second column).

It would have been obvious to a person of ordinary skill in the art to modify Lazar by including acetonitrile and methanol in Lazar's invention. Lazar specifically discloses utilizing a chromatography device. Kaduce teaches that it is known in the art to utilize liquids such as acetonitrile and methanol for these types of devices. Additionally, it would have been obvious to a person of ordinary skill in the art to modify Lazar by utilizing an isocratic elution because it offers many advantages, which include the advantage of having to use only one pump, using a less expensive HPLC equipment compared to HPLC equipment needed for gradient separations, faster processing of multiple samples, and avoiding excessive baseline absorbance changes (page 1401, second column).

### **Double Patenting**

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"



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granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/177,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite substantially the same subject matter, differing in the inclusion of multiple electrodes recited in the instant claims. Both claims recite a substrate, a chromatography column (separation column), and a pump system (electrochemical pump system). It would have been obvious to provide multiple electrodes within the device of claim 1 of application 11/177505 in order to ensure that the electroosmotic flow in the microchannels is moving in the desired direction (Lazar, [0028]). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1743

12/5/06

  
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